Statistical Center for HIV/AIDS Research and Prevention
SCHARP at FRED HUTCH

Study Team Review Guide:

General:

This document is to be used as a database development tool for CDM and the EDC programmer. This document will also serve as an eCRF review tool for the study team during eCRF development. The CDM Lead is the owner of this document. The study team will provide their comments for each eCRF in the appropriate column on the right labeled, "Internal Comments" or "External Comments". Each study member should review those eCRFs that are pertinent to his/her role prior to the Study Orientation Meeting.

Instructions for eCRF Review:

Standard CRFs and their respective data specs have blue tabs in the Build Specs Template.

Clinical eCRFs have purple tabs in the Build Spec Template.

Laboratory eCRFs have green tabs in the Build Spec Template.

Administrative eCRFs have brown tabs in the Build Spec Template.

Behavioral eCRFs have yellow tabs in the Build Spec Template - the Behavioral Forms are still pending input from BRWG and content should be reviewed by study team.

eCRF Data Specifications:

Field OID: Variable name in Medidata Rave. If field OID is empty, existing field has not yet been programmed into Rave.

The Following Tabs Should be Ignored During Internal Review (Items will be hidden for External Review):

Implementation Guide
Folders (study folders to be reviewed at a later date)
Dynamics (used for programming purposes only)
Dictionary (used for programming purposes only)
Coding (used by EDC Programmer and Clinical Coding group)
Derivations (data derivations used by EDC Progammer)
Version

Programming Standards:

All date fields will check for future dates and non conformant data

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Participant Identifier	Participant ID:	Text			
Participant Identifier	NOW	DateTime			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Adverse Event Y/N	Has the participant experienced an adverse event during the study?	RadioButton	Y=Yes; N=No		
Adverse Event Y/N	*If "Yes", update the Adverse Event log.*	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Adverse Event	Date AE reported to site	DateTime			
Adverse Event	Adverse event (AE)	LongText		Record diagnosis (in English), if available.	
Adverse Event	Onset date	DateTime			
Adverse Event	Visit AE was reported	DropDownList	1=Screening 2=Enrollment 3=Visit 3 4=Visit 4 5=Visit 5 6=Visit 6 7=Visit 7 8=Visit 8 9=Visit 9 10=Visit 10 11=Visit 11/Final Contact 12=Interim Visit		
Adverse Event	Interim Visit Code	Text			
Adverse Event	Is the AE still ongoing?	RadioButton	Y=Yes; N=No		
Adverse Event	If "No", outcome date	DateTime			
Adverse Event	Severity grade	DropDownList	1=Grade 1 (Mild) 2=Grade 2 (Moderate) 3=Grade 3 (Severe) 4=Grade 4 (Potentially life-threatening) 5=Grade 5 (Death)		
Adverse Event	Relationship to study product	RadioButton	1=Related 2=Not related		
Adverse Event	Action taken with study product	DropDownList	1=Dose not changed; 2=Dose reduced; 3=Dose increased; 4=Drug withdrawn; 5=Drug interrupted; 98=Not applicable		
Adverse Event	Other actions *Mark "None" or all that apply.* None	CheckBox			
Adverse Event	Medication(s)	CheckBox		Report on Concomitant Medications Log.	
Adverse Event	Therapeutic procedure/surgery	CheckBox			
Adverse Event	Diagnostic procedure	CheckBox			
Adverse Event	Referral	CheckBox			
Adverse Event	Other	CheckBox			
Adverse Event	If "Other", specify (max. 200 characters):	LongText			
Adverse Event	Status/outcome	DropDownList	1=Recovered/resolved; 2=Recovering/resolving; 3=Recovered/resolved with sequelae; 4=Not recovered/not resolved; 5=Fatal; 6=Severity/frequency increased		
Adverse Event	Is this a serious adverse event according to ICH/GCP or protocol guidelines? *If "No", go to "Has or will this AE be reported as an EAE?".* *If "Yes", check all that apply.*	RadioButton	Y=Yes; N=No		
Adverse Event	Results in death	CheckBox			
Adverse Event	Is life-threatening	CheckBox			
Adverse Event	Requires inpatient hospitalization or prolongation of existing hospitalization	CheckBox			
Adverse Event	Results in persistent or significant disability/incapacity	CheckBox			
Adverse Event	Is a congenital anomaly/birth defect	CheckBox			
Adverse Event	Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	CheckBox			
Adverse Event	SAE onset date	DateTime			
Adverse Event	Has or will this AE be reported as an EAE? *If "Yes", provide EAE number below.*	RadioButton	Y=Yes; N=No		
Adverse Event	EAE number *Begin number with 4-digit year, followed by 6-digit EAE number (no dashes or spaces).*	Text			
Adverse Event	Study agent(s)	LongText			
Adverse Event	Was this AE a worsening of a baseline medical condition?	RadioButton	Y=Yes; N=No		
Adverse Event	Comments (max. 450 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Concomitant Medications Y/N	Were any concomitant medications taken?	RadioButton	Y=Yes; N=No		
Concomitant Medications Y/N	*If "Yes", update the Concomitant Medications log.*	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Concomitant Medications	Medication name	LongText			
Concomitant Medications	Indication	LongText			
Concomitant Medications	Date started	DateTime			
Concomitant Medications	Date stopped *Or*	DateTime			
Concomitant Medications	Ongoing	CheckBox		If Date Stopped is provided, Ongoing should not be selected.	
Concomitant Medications	Dose	Text			
Concomitant Medications	Dose units	DropDownList	g=Grams ug=Micrograms mg=Milligrams ml=Millileters CAPSULE=Capsules gtt=Drops PUFF=Puffs SACHET=Sachets SUPPOSITORY=Suppository TABLET=Tablets UNIT=Units UNKNOWN=Unknown OTHER=Other		
Concomitant Medications	If "Other", specify:	LongText			
Concomitant Medications	Frequency	DropDownList	PRN=PRN QD=QD BID=BID TID=TID QID=QID QM=QM QH=QH ONCE=ONCE OTHER=Other		
Concomitant Medications	If "Other", specify:	LongText			
Concomitant Medications	Route	DropDownList	PO=Oral IM=Intramuscular IV=Intravenous TOP=Topical IHL=Inhalation VAG=Vaginal REC=Rectal SC=Subcutaneous OTHER=Other		
Concomitant Medications	If "Other", specify:	LongText			
Concomitant Medications	Taken for a reported AE?	RadioButton	Y=Yes; N=No		
Concomitant Medications	If "Yes", select adverse event.	Dynamic SearchList			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Medical History Y/N	Does the participant have any medical history to report?	RadioButton	Y=Yes; N=No		
Medical History Y/N	*If "Yes", update the Medical History log.*	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Medical History	Date medical history collected	DateTime			
Medical History	Description of medical history condition/event	LongText			
Medical History	Is condition/event gradable?	RadioButton	Y=Yes; N=No		
Medical History	Severity grade	DropDownList	1=Grade 1 (Mild) 2=Grade 2 (Moderate) 3=Grade 3 (Severe) 4=Grade 4 (Potentially life-threatening)		
Medical History	Start date of medical history condition/event	DateTime			
Medical History	Is the condition ongoing?	RadioButton	Y=Yes; N=No		
Medical History	Date medical history/condition ended/resolved	DateTime			
Medical History	Comments (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Discontinuation of Study Product	Date that study product use ended	DateTime			
Discontinuation of Study Product	Primary reason for ending study product use	DropDownList	1=Scheduled study product use period completed 2=Death; 3=Participant refused further participation; 4=Participant is unwilling or unable to comply with required study procedures; 5=Lost to follow-up 6=Investigator decision; 7=Participant refused further study product use; 9=HIV infection; 10=Early study closure; 11=Protocol deviation; 12=Adverse event; 13=Pregnancy or breastfeeding 15=Study terminated by sponsor; 20=Anogenital STI 21=Use of prohibited medications 99=Other, specify		
Discontinuation of Study Product	If "Other", specify:	LongText			
Discontinuation of Study Product	If "Adverse event", select applicable adverse event.	Dynamic SearchList			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Study Termination	Date of study exit	DateTime			
Study Termination	Primary reason for completion/discontinuation	DropDownList	1=Scheduled exit visit/end of study 2=Death 3=Participant refused further participation 4=Participant is unwilling or unable to comply with required study procedures 5=Lost to follow-up 6=Investigator decision 7=Participant refused further study product use 9=HIV infection 10=Early study closure 11=Protocol deviation 12=Adverse event 13=Pregnancy 15=Study terminated by sponsor 99=Other, specify		
Study Termination	If "Other", specify (max. 200 characters):	LongText			
Study Termination	If "Death", enter date of death.	DateTime			
Study Termination	If "Adverse event", select applicable adverse event.	Dynamic SearchList			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Protocol Deviations Log	Site awareness date	DateTime			
Protocol Deviations Log	Deviation date	DateTime			
Protocol Deviations Log	Has or will this deviation be reported to local IRB/EC?	RadioButton	Y=Yes; N=No		
Protocol Deviations Log	Has or will this deviation be reported to DAIDS as a critical event?	RadioButton	Y=Yes; N=No		
Protocol Deviations Log	Type of deviation	SearchList	1=Inappropriate enrollment; 2=Failure to follow randomization or blinding procedures; 3=Study product management deviation; 4=Study product dispensing error; 5=Study product use/non-use deviation; 6=Study product sharing; 7=Study product not returned; 8=Conduct of non-protocol procedure; 9=Improper AE/EAE; 10=Unreported AE; 11=Unreported EAE; 12=Breach of confidentiality; 13=Physical assessment deviation; 14=Lab assessment deviation; 15=Mishandled lab specimen; 16=Staff performing duties that they are not qualified to perform; 17=Questionnaire administration deviation; 18=Counseling deviation; 19=Use of non-IRB/EC-approved materials; 20=Use of excluded concomitant medications, devices, or non-study products; 21=Informed consent process deviation; 22=Visit completed outside of window; 99=Other		
Protocol Deviations Log	Description of deviation	LongText			
Protocol Deviations Log	Plans and/or action taken to address the deviation	LongText			
Protocol Deviations Log	Plans and/or action taken to prevent future occurrences of the deviation	LongText			
Protocol Deviations Log	Deviation reported by	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Protocol Deviations Y/N	Have any protocol deviations been reported?	RadioButton	Y=Yes; N=No		
Protocol Deviations Y/N	*If "Yes", update the Protocol Deviations log.*	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Demographics	Date of birth	DateTime			
Demographics	Age	Text			
Demographics	Sex at birth	RadioButton	M=Male F=Female		
Demographics	Ethnicity	RadioButton (Vertical)	1=Hispanic or Latino 2=Not Hispanic or Latino		
Demographics	Race *Mark all that apply.*	Text			
Demographics	American Indian or Alaska Native	CheckBox			
Demographics	Asian	CheckBox			
Demographics	Black or African American	CheckBox			
Demographics	Native Hawaiian or other Pacific Islander	CheckBox			
Demographics	White	CheckBox			
Demographics	Other	CheckBox			
Demographics	If "Other", specify:	LongText			
Demographics	Gender *Mark all that apply.*	Text			
Demographics	Male	CheckBox			
Demographics	Female	CheckBox			
Demographics	Transgender Male	CheckBox			
Demographics	Transgender Female	CheckBox			
Demographics	Gender Nonconforming/Gender Variant	CheckBox			
Demographics	Self-identify	CheckBox			
Demographics	If "Self-identify", specify:	LongText			
Demographics	Prefer not to answer	CheckBox			
Demographics	How do you identify your sexual orientation?	DropDownList	1=Gay/Lesbian/Homosexual 2=Bisexual 3=Queer 4=Two Spirit 5=Straight/Heterosexual 6=Additional category 7=Not sure 8=Prefer not to answer		
Demographics	If "Additional category", specify:	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Vital Signs	Were vital signs done?	RadioButton	Y=Yes; N=No		
Vital Signs	Date of assessment	DateTime			
Vital Signs	Height	Text			
Vital Signs	Weight	Text			
Vital Signs	Body temperature	Text			
Vital Signs	Systolic blood pressure	Text			
Vital Signs	Diastolic blood pressure	Text			
Vital Signs	Pulse	Text			
Vital Signs	Rate of respiration	Text			

Form Name	Item Text (Field Label)	Response Type	C	Response Options (Dictionary Items	Help Text	External Review Comments
Physical Exam	Was a physical exam performed?	RadioButton		Y=Yes; N=No		
Physical Exam	Date of exam	DateTime				
Physical Exam	**BODY SYSTEM**	Text				
Physical Exam	HEENT	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Neck	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Lymph Nodes	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Heart/Cardiovascular	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Lung/Respiratory	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Abdomen	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Genitourinary	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Extremities	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Neurological	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Skin	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Oral Mucosa	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	General appearance	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Abnormal", specify:	LongText				
Physical Exam	Other system finding	RadioButton		97=Not done; 2=Normal; 3=Abnormal		
Physical Exam	If "Other system finding", specify:	LongText				
Physical Exam	If "Abnormal", specify:	LongText				

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pregnancy Outcome Log	Is the outcome of this pregnancy obtainable? *If "No", end of form.*	RadioButton	Y=Yes; N=No		
Pregnancy Outcome Log	How many pregnancy outcomes resulted from this reported pregnancy?	Text			
Pregnancy Outcome Log	Outcome date	DateTime			
Pregnancy Outcome Log	Place of delivery/outcome	DropdownList	1=Home; 2=Hospital; 3=Clinic; 4=Unknown; 5=Other		
Pregnancy Outcome Log	If "Other", specify:	LongText			
Pregnancy Outcome Log	Specify outcome *If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth", go to "Method".*	DropdownList	1=Full term live birth (greater than or equal to 37 weeks); 2=Premature live birth (less than 37 weeks); 3=Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks); 4=Spontaneous abortion (less than 20 weeks); 5=Ectopic pregnancy; 6=Therapeutic/elective abortion; 99=Other	If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on the AE Log. Complete an EAE reporting form, if applicable.	
Pregnancy Outcome Log	If "Other", specify:	LongText			
Pregnancy Outcome Log	Method *If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?"*	DropdownList	1=C-section; 2=Standard vaginal; 3=Operative vaginal; 4=Vaginal		
Pregnancy Outcome Log	Provide a brief narrative of the circumstances (max. 400 characters).	LongText			
Pregnancy Outcome Log	Were there any complications related to the pregnancy outcome? *If "No", skip to "Were any fetal/infant congenital anomalies identified?".*	RadioButton	Y=Yes; N=No		
Pregnancy Outcome Log	**Delivery-related complications.** *Mark "None" or all that apply.* None	CheckBox			
Pregnancy Outcome Log	Intrapartum hemorrhage	CheckBox			
Pregnancy Outcome Log	Postpartum hemorrhage	CheckBox			
Pregnancy Outcome Log	Non-reassuring fetal status	CheckBox			
Pregnancy Outcome Log	Chorioamnionitis	CheckBox			
Pregnancy Outcome Log	Other	CheckBox			
Pregnancy Outcome Log	If "Other", specify:	LongText			
Pregnancy Outcome Log	**Non-delivery related complications.** *Mark "None" or all that apply.* None	CheckBox			
Pregnancy Outcome Log	Hypertensive disorders of pregnancy	CheckBox			
Pregnancy Outcome Log	Gestational diabetes	CheckBox			
Pregnancy Outcome Log	Other	CheckBox			
Pregnancy Outcome Log	If "Other", specify:	LongText			
Pregnancy Outcome Log	Were any fetal/infant congenital anomalies identified? *Mark all that apply.* *If "No" or "Unknown", go to "Complete the infant items below for live births only."*	DropDownList	Y=Yes; N=No; NS=Not assessed; UNK=Unknown		
Pregnancy Outcome Log	Central nervous system, cranio-facial	CheckBox			
Pregnancy Outcome Log	Central nervous system, spinal	CheckBox			
Pregnancy Outcome Log	Cardiovascular	CheckBox			
Pregnancy Outcome Log	Renal	CheckBox			
Pregnancy Outcome Log	Gastrointestinal	CheckBox			
Pregnancy Outcome Log	Pulmonary	CheckBox			
Pregnancy Outcome Log	Musculoskeletal/extremities	CheckBox			
Pregnancy Outcome Log	Physical defect	CheckBox			
Pregnancy Outcome Log	Skin	CheckBox			
Pregnancy Outcome Log	Genitourinary	CheckBox			
Pregnancy Outcome Log	Chromosomal	CheckBox			
Pregnancy Outcome Log	Cranio-facial (structural)	CheckBox			
Pregnancy Outcome Log	Hematologic	CheckBox			
Pregnancy Outcome Log	Infectious	CheckBox			
Pregnancy Outcome Log	Endocrine/metabolic	CheckBox			
Pregnancy Outcome Log	Other	CheckBox			
Pregnancy Outcome Log	Describe congenital anomaly/defect (max. 200 characters).	LongText			
Pregnancy Outcome Log	*If "Yes", select adverse event. OR Specify congenital anomaly/defect AE.* *Complete AE Log and EAE Reporting form.*	Dynamic SearchList			
Pregnancy Outcome Log	**Complete the infant items below for live births only. Otherwise, end of form.** Infant sex	RadioButton	M=Male; F=Female		
Pregnancy Outcome Log	Infant birth weight *Or*	Text			
Pregnancy Outcome Log	Infant birth weight unavailable	CheckBox			
Pregnancy Outcome Log	Infant birth weight unit	Text			
Pregnancy Outcome Log	Infant birth length *Or*	Text			
Pregnancy Outcome Log	Infant birth length unavailable	CheckBox			
Pregnancy Outcome Log	Infant birth length unit	Text			
Pregnancy Outcome Log	Infant birth head circumference *Or*	Text			
Pregnancy Outcome Log	Infant birth head circumference unavailable	CheckBox			
Pregnancy Outcome Log	Infant birth head circumference unit	Text			
Pregnancy Outcome Log	Infant birth abdominal circumference *Or*	Text			
Pregnancy Outcome Log	Infant birth abdominal circumference unavailable	CheckBox			
Pregnancy Outcome Log	Infant birth abdominal circumference unit	Text			
Pregnancy Outcome Log	Infant gestational age by examination in weeks	Text			
Pregnancy Outcome Log	Infant gestational age by examination in weeks Unit	Text			
Pregnancy Outcome Log	Infant gestational age by examination in days *Or*	Text			
Pregnancy Outcome Log	Infant gestational age by examination in Days Unit	Text			
Pregnancy Outcome Log	Infant gestational age by examination unavailable *If unavailable, end of form.*	CheckBox			
Pregnancy Outcome Log	Method used to determine gestational age	DropDownList	1=Ballard; 2=Dubowitz; 99=Other		
Pregnancy Outcome Log	If "Other", specify (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pregnancy Test Results	Was a pregnancy test done?	RadioButton	Y=Yes; N=No		
Pregnancy Test Results	Collection date	DateTime			
Pregnancy Test Results	Pregnancy test result	RadioButton	1=Positive; 2=Negative		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pregnancy History	Date pregnancy history collected	DateTime			
Pregnancy History	Has the participant ever been pregnant before?	RadioButton	Y=Yes; N=No		
Pregnancy History	*If "No", end of form.*	Text			
Pregnancy History	Number of full term live births (>=37 weeks)	Text			
Pregnancy History	Number of premature live births (Less than 37 weeks)	Text			
Pregnancy History	Number of spontaneous fetal deaths and/or still births (>=20 weeks)	Text			
Pregnancy History	Number of spontaneous abortions (Less than 20 weeks)	Text			
Pregnancy History	Number of therapeutic/elective abortions	Text			
Pregnancy History	Number of ectopic pregnancies	Text			
Pregnancy History	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	RadioButton	Y=Yes; N=No		
Pregnancy History	If "Yes", specify (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pregnancy Report	Date pregnancy reported to site	DateTime			
Pregnancy Report	Visit at which this pregnancy was reported	DropDownList	1=Screening 2=Enrollment 3=Visit 3 4=Visit 4 5=Visit 5 6=Visit 6 7=Visit 7 8=Visit 8 9=Visit 9 10=Visit 10 11=Visit 11/Final Contact 12=Interim Visit		
Pregnancy Report	If "Interim visit", specify Interim visit code	Text			
Pregnancy Report	Date of onset of last menstrual period	DateTime			
Pregnancy Report	*Or*	Text			
Pregnancy Report	Amenorrheic for past 6 months	CheckBox			
Pregnancy Report	Estimated date of delivery	DateTime			
Pregnancy Report	What primary information was used to estimate the date of delivery?	DropDownList	1=Last menstrual period; 2=Initial ultrasound <20 weeks; 3=Initial ultrasound >= 20 weeks; 4= Physical examination; 5=Conception date by assisted reproduction; 99=Other		
Pregnancy Report	If "Other", specify:	LongText			
Pregnancy Report	Is this the participant's first pregnancy since enrollment in this study?	RadioButton	Y=Yes; N=No		
Pregnancy Report	*If "Yes", complete Pregnancy History form.*	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Anorectal Exam	Was anorectal exam done?	RadioButton	Y=Yes; N=No		
Anorectal Exam	Anorectal exam date	DateTime			
Anorectal Exam	**PERIANAL EXAMINATION**	Text			
Anorectal Exam	Perianal examination findings	DropDownList	99=Not done; 2=No abnormal findings; 3=Abnormal findings		
Anorectal Exam	If "Abnormal findings", select all that apply:	Text			
Anorectal Exam	Warts	CheckBox			
Anorectal Exam	Fissure	CheckBox			
Anorectal Exam	Ulceration	CheckBox			
Anorectal Exam	Pigmentation	CheckBox			
Anorectal Exam	Hemorrhoids	CheckBox			
Anorectal Exam	Skin tags	CheckBox			
Anorectal Exam	Leukoplakia	CheckBox			
Anorectal Exam	Fistula	CheckBox			
Anorectal Exam	Petechiae (less than 3 mm)	CheckBox			
Anorectal Exam	Purpura (0.3 to 1 cm)	CheckBox			
Anorectal Exam	Ecchymosis (greater than 1 cm)	CheckBox			
Anorectal Exam	Discharge	CheckBox			
Anorectal Exam	Erythema	CheckBox			
Anorectal Exam	Bleeding	CheckBox			
Anorectal Exam	Other abnormal findings	CheckBox			
Anorectal Exam	If "Other abnormal findings", specify:	LongText			
Anorectal Exam	**DIGITAL RECTAL EXAMINATION**	Text			
Anorectal Exam	Digital rectal examination findings	DropDownList	99=Not done; 2=No abnormal findings; 3=Abnormal findings		
Anorectal Exam	If "Abnormal findings", specify:	LongText			
Anorectal Exam	**ANOSCOPY**	Text			
Anorectal Exam	Rectal mucosa findings	DropDownList	99=Not done; 2=No abnormal findings; 3=Abnormal findings		
Anorectal Exam	If "Abnormal findings", select all that apply:	Text			
Anorectal Exam	Erythema	CheckBox			
Anorectal Exam	Abnormal vessels	CheckBox			
Anorectal Exam	Ulceration	CheckBox			
Anorectal Exam	Friability	CheckBox			
Anorectal Exam	Bleeding	CheckBox			
Anorectal Exam	Discharge	CheckBox			
Anorectal Exam	Polyps	CheckBox			
Anorectal Exam	Hemorrhoids	CheckBox			
Anorectal Exam	Other abnormal findings	CheckBox			
Anorectal Exam	If "Other abnormal findings", specify:	LongText			
Anorectal Exam	**SIGMOIDOSCOPY**	Text			
Anorectal Exam	Sigmoidoscopy findings	DropDownList	99=Not done; 2=No abnormal findings; 3=Abnormal findings		
Anorectal Exam	If "Abnormal findings", select all that apply:	Text			
Anorectal Exam	Erythema	CheckBox			
Anorectal Exam	Abnormal vessels	CheckBox			
Anorectal Exam	Ulceration	CheckBox			
Anorectal Exam	Friability	CheckBox			
Anorectal Exam	Bleeding	CheckBox			
Anorectal Exam	Discharge	CheckBox			
Anorectal Exam	Polyps	CheckBox			
Anorectal Exam	Hemorrhoids	CheckBox			
Anorectal Exam	Other abnormal findings	CheckBox			
Anorectal Exam	If "Other abnormal findings", specify:	LongText			
Anorectal Exam	Were any new anorectal AE findings reported at this visit?	RadioButton	Y=Yes; N=No		
Anorectal Exam	Adverse event #1	Dynamic SearchList			
Anorectal Exam	Adverse event #2	Dynamic SearchList			
Anorectal Exam	Adverse event #3	Dynamic SearchList			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pelvic Exam	Pelvic exam assessment	DropDownList	99=Not done; 2=No abnormal findings; 3=Abnormal findings		
Pelvic Exam	Pelvic exam date	DateTime			
Pelvic Exam	*If "Abnormal findings", select all that apply:*	Text			
Pelvic Exam	**VULVAR**	Text			
Pelvic Exam	Vulvar edema	CheckBox			
Pelvic Exam	Vulvar erythema	CheckBox			
Pelvic Exam	Vulvar rash	CheckBox			
Pelvic Exam	Vulvar tenderness	CheckBox			
Pelvic Exam	Bartholin's or Skene's gland abnormality	CheckBox			
Pelvic Exam	Vulvar ulcer	CheckBox			
Pelvic Exam	Vulvar blister	CheckBox			
Pelvic Exam	Vulvar pustule	CheckBox			
Pelvic Exam	Vulvar peeling	CheckBox			
Pelvic Exam	Vulvar ecchymosis	CheckBox			
Pelvic Exam	**VAGINAL**	Text			
Pelvic Exam	Vaginal edema	CheckBox			
Pelvic Exam	Vaginal erythema	CheckBox			
Pelvic Exam	Vaginal masses (polyps, myomas, possible malignancy)	CheckBox			
Pelvic Exam	Vaginal abrasions or lacerations	CheckBox			
Pelvic Exam	Vaginal tenderness	CheckBox			
Pelvic Exam	Vaginal ulcer	CheckBox			
Pelvic Exam	Vaginal blister	CheckBox			
Pelvic Exam	Vaginal pustule	CheckBox			
Pelvic Exam	Vaginal peeling	CheckBox			
Pelvic Exam	Vaginal ecchymosis	CheckBox			
Pelvic Exam	Abnormal vaginal discharge	DropDownList	1=Slight; 2=Moderate; 3=Pooling		
Pelvic Exam	**CERVICAL**	Text			
Pelvic Exam	Cervical edema and/or friability	CheckBox			
Pelvic Exam	Cervical erythema	CheckBox			
Pelvic Exam	Cervical masses (polyps, myomas, possible malignancy)	CheckBox			
Pelvic Exam	Cervical motion tenderness	CheckBox			
Pelvic Exam	Cervical discharge	CheckBox			
Pelvic Exam	Cervical ulcer	CheckBox			
Pelvic Exam	Cervical blister	CheckBox			
Pelvic Exam	Cervical pustule	CheckBox			
Pelvic Exam	Cervical peeling	CheckBox			
Pelvic Exam	Cervical ecchymosis	CheckBox			
Pelvic Exam	**GENERAL/OTHER**	Text			
Pelvic Exam	Odor (vaginal)	CheckBox			
Pelvic Exam	Condyloma	CheckBox			
Pelvic Exam	If "Condyloma", specify location:	LongText			
Pelvic Exam	Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	CheckBox			
Pelvic Exam	Uterine masses (based on bimanual exam)	CheckBox			
Pelvic Exam	Uterine tenderness	CheckBox			
Pelvic Exam	Adnexal tenderness	CheckBox			
Pelvic Exam	Abnormal blood or bleeding	CheckBox			
Pelvic Exam	If "Abnormal blood or bleeding", specify:	LongText			
Pelvic Exam	Other abnormal findings	CheckBox			
Pelvic Exam	If "Other abnormal findings", specify:	LongText			
Pelvic Exam	If "Other abnormal findings", specify anatomical location:	LongText			
Pelvic Exam	Complete or update Baseline Medical Conditions Log or Adverse Event Log, as applicable.	Text			
Pelvic Exam	Were any new pelvic finding AEs reported at this visit?	RadioButton	Y=Yes; N=No		
Pelvic Exam	Adverse event #1	Dynamic SearchList			
Pelvic Exam	Adverse event #2	Dynamic SearchList			
Pelvic Exam	Adverse event #3	Dynamic SearchList			
Pelvic Exam	Cervical ectopy (%)	DropDownList	1=0% 2=1-25% 3=26-50% 4=51-75% 5=76-100% 99=Not done		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Product Hold Summary	Does the participant have any clinical product holds to be applied?	RadioButton	Yes No		
Product Hold Summary	**If Yes, complete the Product Hold form**	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Product Hold Log	Date when study product hold was intiated:	DateTime	NA		
Product Hold Log	Why is study product being held?	RadioButton	1=Reactive rapid HIV test 2=Adverse Event 3=Reported use of PEP or PrEP 4=Pregnancy 5=Breastfeeding 6=Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee 99=Other		
Product Hold Log	Other, specify:	LongText	NA		
Product Hold Log	Adverse Event:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Date of last study product use:	DateTime	NA		
Product Hold Log	Was the participant instructed to resume study product use? **If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Product Discontinuation form.**	DropDown	1=Yes 2=No - Hold continuing for another reason 3=No - Early termination 4=No - Hold continuing at scheduled PUEV 5=No - Permanently discontinued		
Product Hold Log	Date study product resumed	DateTime			
Product Hold Log	Date study product hold continuing for another reason	DateTime			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
STI Tests	Was a pharyngeal sample collected for N. gonorrhea and C. trachomatis testing?	RadioButton	Yes No		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - Pharyngeal test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - Pharyngeal test result	RadioButton	1=Positive; 2=Negative		
STI Tests	Was a pelvic sample collected for N. gonorrhea, C. trachomatis, and trichomonas vaginalis testing?	RadioButton	Yes No		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - Pelvic test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - Pelvic test result	RadioButton	1=Positive; 2=Negative		
STI Tests	trichomonas vaginalis - Pelvic test result	RadioButton	1=Positive; 2=Negative		
STI Tests	Was a sample collected for Syphilis testing?	RadioButton	Yes No		
STI Tests	Collection date	DateTime			
STI Tests	Syphilis screening test	RadioButton (Horiz	1=Non-reactive 2=Reactive 3=Not reported		
STI Tests	Syphilis titer	Text			
STI Tests	Syphilis confirmatory test	DropDownList	1=Postive 2=Negative 3=Indeterminate 4=Not done		
STI Tests	Was a urine sample collected for N. gonorrhea and C. trachomatis testing?	RadioButton	Yes No		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - URINE test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - URINE test result	RadioButton	1=Positive; 2=Negative		
STI Tests	Was a rectal swab sample collected for N. gonorrhea and C. trachomatis testing?	RadioButton	Yes No		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - RECTAL SWAB test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - RECTAL SWAB test result	RadioButton	1=Positive; 2=Negative		
STI Tests	Was the participant diagnosed with asymptomatic BV?	RadioButton	Yes No		
STI Tests	Was the participant diagnosed with asymptomatic candida?	RadioButton	Yes No		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Chemistry Panel	Was a sample collected for serum chemistries?	RadioButton	Y=Yes; N=No		
Chemistry Panel	Specimen collection date	DateTime			
Chemistry Panel	**LIVER FUNCTION TESTS**	Text			
Chemistry Panel	AST (SGOT) result	Text			
Chemistry Panel	AST (SGOT) severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Chemistry Panel	AST (SGOT) severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Chemistry Panel	AST (SGOT) adverse event	Dynamic SearchList			
Chemistry Panel	Not reportable as an adverse event	CheckBox			
Chemistry Panel	ALT (SGPT) result	Text			
Chemistry Panel	ALT (SGPT) severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Chemistry Panel	ALT (SGPT) severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Chemistry Panel	ALT (SGPT) adverse event	Dynamic SearchList			
Chemistry Panel	Not reportable as an adverse event	CheckBox			
Chemistry Panel	**RENAL FUNCTION TESTS**	Text			
Chemistry Panel	Creatinine result	Text			
Chemistry Panel	Creatinine severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Chemistry Panel	Creatinine severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Chemistry Panel	Creatinine adverse event	Dynamic SearchList			
Chemistry Panel	Not reportable as an adverse event	CheckBox			
Chemistry Panel	Comments (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Hematology	**HEMOGRAM**	Text			
Hematology	Was a hematology sample collected?	RadioButton	Y=Yes; N=No		
Hematology	Hematology collection date	DateTime			
Hematology	Hemoglobin	Text			
Hematology	Hemoglobin severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Hemoglobin severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Hemoglobin adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	Hematocrit	Text			
Hematology	MCV	Text			
Hematology	Platelets	Text			
Hematology	Platelets severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Platelets severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Platelets adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	WBC	Text			
Hematology	WBC severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	WBC severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	WBC adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	**DIFFERENTIAL**	Text			
Hematology	Was a differential done?	RadioButton	Y=Yes; N=No		
Hematology	Differential collection date	DateTime			
Hematology	Neutrophils	Text			
Hematology	Neutrophils severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Neutrophils severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Neutrophils adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	Lymphocytes	Text			
Hematology	Lymphocytes severity grade	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Lymphocytes severity grade - calculated	DropDownList	1=Grade 1 (Mild); 2=Grade 2 (Moderate); 3=Grade 3 (Severe); 4=Grade 4 (Potentially life-threatening); 95=Not gradable		
Hematology	Lymphocytes adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	Monocytes	Text			
Hematology	Eosinophils	Text			
Hematology	Basophils	Text			
Hematology	Comments (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
HIV Test Results	**Rapid HIV test 1**	Text			
HIV Test Results	Was Rapid HIV test sample 1 collected for testing?	RadioButton	Yes No		
HIV Test Results	If "No", skip to Rapid HIV test 2.				
HIV Test Results	Rapid HIV test 1 Kit	DropDownList	1=AlereTM HIV Combo 2=Oraquick ADVANCE HIV-1/2 3=Uni-Gold Recombigen HIV-1/2 4=Alere Determine 5=Other		
HIV Test Results	If "Other", specify:	LongText			
HIV Test Results	Rapid HIV test 1 collection date	DateTime			
HIV Test Results	Rapid HIV test 1	DropDownList	1=Antibody positive 2=Antigen positive 3=Antibody and antigen positive 4=Negative	If antibody positive, antigen positive, or antibody and antigen positive, complete Product Hold form.	
HIV Test Results	**Rapid HIV test 2**	Text			
HIV Test Results	Was Rapid HIV test sample 2 collected for testing?	RadioButton	Yes No		
HIV Test Results	If "No", end of form.				
HIV Test Results	Rapid HIV test 2 Kit	DropDownList	1=AlereTM HIV Combo 2=Oraquick ADVANCE HIV-1/2 3=Uni-Gold Recombigen HIV-1/2 4=Alere Determine 5=Other		
HIV Test Results	If "Other", specify:	LongText			
HIV Test Results	Rapid HIV test 2 collection date	DateTime	NA		
HIV Test Results	Rapid HIV test 2	DropDownList	1=Antibody positive 2=Antigen positive 3=Antibody and antigen positive 4=Negative	If antibody positive, antigen positive, or antibody and antigen positive, complete Prodcut Hold form.	
HIV Test Results	**If at least one Rapid HIV tests is positive, complete the HIV Confirmatory Test Result form.**	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
HIV Confirmatory Results	**ABSOLUTE CD4+**	Text			
HIV Confirmatory Results	Were Absolute CD4+ collected for testing?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	Absolute CD4+	Text			
HIV Confirmatory Results	Absolute CD4+ unit	Text			
HIV Confirmatory Results	Unable to analyze	CheckBox			
HIV Confirmatory Results	**CD4 %**	Text			
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	CD4 %	Text			
HIV Confirmatory Results	CD4 % unit	Text			
HIV Confirmatory Results	Unable to analyze	CheckBox			
HIV Confirmatory Results	**T CELL SUBSETS**	Text			
HIV Confirmatory Results	Were T Cell Subsets collected for testing?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	*If "No", go to "HIV RNA".*	Text			
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	T Cell subsets	RadioButton	1=Positive; 2=Negative		
HIV Confirmatory Results	**HIV RNA**	Text			
HIV Confirmatory Results	Was HIV RNA PCR testing completed?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	Operator	RadioButton	1=>; 2=<; 3==		
HIV Confirmatory Results	HIV RNA PCR	Text			
HIV Confirmatory Results	HIV RNA PCR unit	Text			
HIV Confirmatory Results	HIV RNA PCR target not detected	CheckBox			
HIV Confirmatory Results	HIV RNA PCR kit	DropDownList	Depends on the PCR Kit		
HIV Confirmatory Results	HIV RNA PCR kit lower limit of detection	RadioButton	Depends on the PCR Kit		
HIV Confirmatory Results	HIV RNA PCR kit lower limit of detection text	Text			
HIV Confirmatory Results	HIV RNA PCR kit lower limit of detection unit	Text			
HIV Confirmatory Results	**GEENIUS HIV-1/2 CONFIRMATORY TEST**	Text			
HIV Confirmatory Results	Was Geenius HIV-1/2 confirmatory test collected for testing?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	Geenius HIV-1/2 result	DropDownList	1=HIV negative; 2=HIV-1 indeterminate; 3=HIV-2 indeterminate; 4=HIV-1 positive; 5=HIV-2 positive; 6=HIV-2 positive with HIV-1 cross-reactivity; 7=HIV positive undifferentiatied (untypeable)		
HIV Confirmatory Results	Final HIV status	DropDownList	1=HIV uninfected; 2=HIV infected; 3=Pending		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Specimen Collection and Storage	Specimen type	DropDown List	2=Blood for PK; 3=Blood for PK - 1 hr; 4=Blood for PK - 2 hrs; 5=Blood for PK - 4 hrs; 6=Blood for PK - 6 hrs; 7=CVF for PK; 8=CVF for PK - 2 hrs; 9=CVF for PK - 4 hrs; 10=CVF for PK - 6 hrs; 11=CVF for PD; 12=CVF for PD - 2 hrs; 13=CVF for microflora; 14=CVF for microflora - 2 hrs; 15=Rectal fluid for PK; 16=Rectal fluid for PK - 2 hrs; 17=Rectal fluid for PK - 4 hrs; 18=Rectal fluid for PK - 6 hrs; 19=Rectal fluid for PD; 20=Rectal fluid for PD - 2 hrs; 21=Rectal fluid for microbiome; 22=Rectal fluid for microbiome - 2 hrs; 23=Rectal enema prior to biopsy collection; 24=Rectal tissue for PK; 25=Rectal tissue for PK - 2 hrs; 26=Rectal tissue for PD; 27=Rectal tissue for PD - 2 hrs; 28=Rectal tissue for biomarkers;		
Specimen Collection and Storage	Was specimen collected?	RadioButton	Y=Yes; N=No		
Specimen Collection and Storage	If "No", record reason why sample was not collected (max. 200 characters).	LongText			
Specimen Collection and Storage	Specimen collection date	DateTime			
Specimen Collection and Storage	Specimen collection time	DateTime			
Specimen Collection and Storage	Was sample stored?	RadioButton	1=Stored; 2=Not stored		
Specimen Collection and Storage	If "No", record reason why sample was not stored (max. 200 characters).	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Specimen Collection and Storage (Group 1)	Specimen type	DropDown List	1=Plasma for archive; 2=Blood for PK; 3=Blood for PK - 1 hr; 4=Blood for PK - 2 hrs; 5=Blood for PK - 4 hrs; 6=Blood for PK - 6 hrs; 7=CVF for PK; 8=CVF for PK - 2 hrs; 9=CVF for PK - 6 hrs; 10=CVF for PD; 11=CVF for PD - 2 hrs; 12=CVF for microflora; 13=CVF for microflora - 2 hrs; 14=Rectal fluid for PK; 15=Rectal fluid for PK - 2 hrs; 16=Rectal fluid for PK - 6 hrs; 17=Rectal fluid for PD; 18=Rectal fluid for PD - 2 hrs; 19=Rectal fluid for microbiome; 20=Rectal fluid for microbiome - 2 hrs; 21=Rectal enema prior to biopsy collection; 22=Rectal tissue for PK; 23=Rectal tissue for PK - 2 hrs; 24=Rectal tissue for PD; 25=Rectal tissue for PD - 2 hrs; 26=Rectal tissue for biomarkers; 27=Rectal tissue for biomarkers - 2 hrs		
Specimen Collection and Storage (Group 1)	Was specimen collected?	RadioButton	Y=Yes; N=No		
Specimen Collection and Storage (Group 1)	If "No", record reason why sample was not collected (max. 200 characters).	LongText			
Specimen Collection and Storage (Group 1)	Specimen collection date	DateTime			
Specimen Collection and Storage (Group 1)	Specimen collection time	DateTime			
Specimen Collection and Storage (Group 1)	Was sample stored?	RadioButton	1=Stored; 2=Not stored		
Specimen Collection and Storage (Group 1)	If "No", record reason why sample was not stored (max. 200 characters).	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Specimen Collection and Storage	Specimen type	DropDown List	1=Plasma for archive; 2=Blood for PK; 3=Blood for PK - 1 hr; 4=Blood for PK - 2 hrs; 5=Blood for PK - 4 hrs; 6=Blood for PK - 6 hrs; 7=CVF for PK; 8=CVF for PK - 4 hrs; 9=CVF for PD; 10=CVF for microflora; 11=Rectal fluid for PK; 12=Rectal fluid for PK - 4 hrs; 13=Rectal fluid for PD; 14=Rectal fluid for microbiome; 15=Rectal enema prior to biopsy collection; 16=Rectal tissue for PK; 17=Rectal tissue for PD; 18=Rectal tissue for biomarkers;		
Specimen Collection and Storage	Was specimen collected?	RadioButton	Y=Yes; N=No		
Specimen Collection and Storage	If "No", record reason why sample was not collected (max. 200 characters).	LongText			
Specimen Collection and Storage	Specimen collection date	DateTime			
Specimen Collection and Storage	Specimen collection time	DateTime			
Specimen Collection and Storage	Was sample stored?	RadioButton	1=Stored; 2=Not stored		
Specimen Collection and Storage	If "No", record reason why sample was not stored (max. 200 characters).	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Inclusion Exclusion Criteria	Did the participant meet all eligibility criteria?	RadioButton	Y=Yes; N=No		
Inclusion Exclusion Criteria	Eligibility status	DropDownList	1=Eligible and enrolled 2=Eligible/Not enrolled 3=Ineligible 4=Incomplete screening		
Inclusion Exclusion Criteria	***If "Eligible and enrolled", or "Incomplete screening", end of form.***	Text			
Inclusion Exclusion Criteria	Select reason(s) why participant is ineligible.	DropDownList	See data dictionary tab (study build specific)		
Inclusion Exclusion Criteria	If "Investigator decision", specify (max. 200 characters):	LongText			
Inclusion Exclusion Criteria	If eligible, but participant declined enrollment, specify reason:	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Enrollment	Date the participant marked or signed the study screening and enrollment consent form	DateTime			
Enrollment	Did the participant consent to long-term specimen storage and future testing?	RadioButton	Yes No		
Enrollment	Sample Collection Schedule Assignment	RadioButton	1=Group 1 2=Group 2		
Enrollment	Is this a replacement participant?	RadioButton	Yes No		
Enrollment	PTID of participant being replaced	Text	NA		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Screening Date of Visit	Screening visit date	DateTime	NA		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Randomization	Is the participant ready to be randomized?	RadioButton	Y=Yes; N=No		
Randomization	Randomization date and time	DateTime			
Randomization	Randomization date	DateTime			
Randomization	Randomization ID	Text			
Randomization	Regime name	Text			
Randomization	Regime ratio	Text			
Randomization	Stratum name	Text			
Randomization	Blinded	Text			
Randomization	TSDV hidden variable	Text			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Follow-up Visit Y/N	Did the participant complete this visit?	RadioButton	Yes No		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Follow-up Visit Summa	Visit date:	DateTime			
Follow-up Visit Summa	Was this a PK/PD Sampling Visit?	RadioButton	Yes No		
Follow-up Visit Summa	Was study product permanently discontinued (scheduled or early) at this visit?	RadioButton	Yes No		
Follow-up Visit Summa	Did the participant exit/terminate the study at this visit?	RadioButton	Yes No		
Follow-up Visit Summa	Were any new adverse events (AEs) reported at this visit?	RadioButton	Yes No		
Follow-up Visit Summa	Is the participant taking any concomitant medications that have not been previously reported?	RadioButton	Yes No		
Follow-up Visit Summa	Have any protocol deviations been reported at this visit?	RadioButton	Yes No		
Follow-up Visit Summa	Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	RadioButton	Yes No		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Interim Visit Summary	Visit date	DateTime			
Interim Visit Summary	Interim visit code	Text			
Interim Visit Summary	Was study product use permanently discontinued (scheduled or early) at this visit?	RadioButton	Yes No		
Interim Visit Summary	Did the participant exit/terminate the study at this visit?	RadioButton	Yes No		
Interim Visit Summary	Were any new adverse events (AEs) reported at this visit?	RadioButton	Yes No		
Interim Visit Summary	Is the participant taking any concomitant medications that have not been previously reported?	RadioButton	Yes No		
Interim Visit Summary	Have any protocol deviations been reported at this visit?	RadioButton	Yes No		
Interim Visit Summary	Reason for interim visit (Select all that apply.)	Text			
Interim Visit Summary	AE report or follow-up	CheckBox			
Interim Visit Summary	Completion of missed visit procedures	CheckBox			
Interim Visit Summary	If completion of missed visit procedures, for which visit are procedures being made up?	DropDownList	1=Visit 3 2=Visit 4 3=Visit 5 4=Visit 6 5=Visit 7 6=Visit 8 7=Visit 9 8=Visit 10 9=Visit 11/Final Contact 10=Interim Visit		
Interim Visit Summary	Other	CheckBox			
Interim Visit Summary	If other, specify	LongText			
Interim Visit Summary	What study procedures were completed at this visit? Select all that apply.	Text			
Interim Visit Summary	Vital signs	CheckBox			
Interim Visit Summary	Physical exam	CheckBox			
Interim Visit Summary	Pelvic exam	CheckBox			
Interim Visit Summary	Anorectal exam	CheckBox			
Interim Visit Summary	Specimen Collection and Storage	CheckBox			
Interim Visit Summary	Pregnancy test	CheckBox			
Interim Visit Summary	Hematology	CheckBox			
Interim Visit Summary	Chemistry Panel	CheckBox			
Interim Visit Summary	HIV test(s)	CheckBox			
Interim Visit Summary	STI test(s) (other than HIV)	CheckBox			
Interim Visit Summary	CASI	CheckBox			
Interim Visit Summary	Participant Replacement	Checkbox			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Additional Study Procedures	Anorectal Exam	Checkbox			
Additional Study Procedures	Behavioral Assessment	Checkbox			
Additional Study Procedures	CASI Tracking	Checkbox			
Additional Study Procedures	Chemistry Panel	Checkbox			
Additional Study Procedures	Demographics	Checkbox			
Additional Study Procedures	Hematology	Checkbox			
Additional Study Procedures	HIV Confirmatory Results	Checkbox			
Additional Study Procedures	Pelvic Exam	Checkbox			
Additional Study Procedures	Physical Examination	Checkbox			
Additional Study Procedures	Pregnancy Test Results	Checkbox			
Additional Study Procedures	Specimen Collection and Storage	Checkbox			
Additional Study Procedures	STI Tests	Checkbox			
Additional Study Procedures	Vital Signs	Checkbox			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Missed Visit	Target visit date	DateTime			
Missed Visit	Reason visit was missed	DropDownList	1=Unable to contact participant; 2=Participant unable to schedule visit within window; 3=Participant refused visit; 4=Participant incarcerated; 5=Participant admitted to healthcare facility; 6=Participant withdrew from study; 7=Participant deceased; 99=Other		
Missed Visit	If "Other", specify:	LongText			
Missed Visit	Steps taken to address the missed visit (corrective action plan)	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Participant Replacement Assessment	Date of assessment	Date Time			
Participant Replacement Assessment	Does this participant meet protocol-specified criteria for replacement?	RadioButton	Yes No		
Participant Replacement Assessment	Why is this participant being replaced?	Dropdown List	1=None of the doses administered (e.g., due to non-adherence or permanent discontinuation) 2=Early termination (e.g., due to participant voluntarily withdrawing from the study, death, lost to follow-up, relocation, or permanent discontinuation) 3=Other		
Participant Replacement Assessment	If other, specify	Text	NA	2	

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Behavioral Assessment	Was a CASI questionnaire or IDI completed at this visit?	RadioButton	Yes No		
Behavioral Assessment	If no, please explain:	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
CASI Tracking	CASI collection date	DateTime			
CASI Tracking	CASI ID	Text			
CASI Tracking	Which questionnaire was completed?	Dropdown List	1=Visit 2 Baseline CASI 2=Visit 4 Follow-Up CASI 3=Visit 8 Follow-Up CASI 4=Visit 10 IDI		
CASI Tracking	Were there any problems or issues related to the administration or completion of the questionnaire?	RadioButton			
CASI Tracking	If yes, please describe	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Dose Administration	Visit Number	Dropdown List	1=Visit 3 2=Visit 7		
Dose Administration	Date gel application administered	DateTime	NA		
Dose Administration	Time gel application administered	Time	NA		
Dose Administration	Dosage Administered	Dropdown List	1=1 TAF/EVG insert 2=2 TAF/EVG inserts		

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pharmacy Dispensation	Which visit was study product dispensed:	DropDown	1=Visit 3 2=Visit 7		
Pharmacy Dispensation	Date study product dispensed:	DateTime	NA		
Pharmacy Dispensation	Dosage dispensed	DropDown	1=1 TAF/EVG insert 2=2 TAF/EVG inserts		

Data Dictionary Name	Coded Data	User Data String
AEACN	1	Dose not changed
AEACN	2	Dose reduced
AEACN	3	Dose increased
AEACN	4	Drug withdrawn
AEACN	5	Drug interrupted
AEACN	6	Not applicable
AEACNV	1	No change
AEACNV	2	Held
AEACNV	3	Permanently discontinued
AEACNV	4	Not applicable
AEOUT	1	Recovered/resolved
AEOUT	2	Recovering/resolving
AEOUT	3	Recovered/resolved with sequelae
AEOUT	4	Not recovered/not resolved
AEOUT	5	Fatal
AEOUTV	1	Resolved
AEOUTV	2	Recovering/resolving
AEOUTV	3	Recovered with sequelae
AEOUTV	4	Continuing
AEOUTV	5	Death
AEOUTV	6	Severity/frequency increased
AEREL	1	Related
AEREL	2	Not related
AESEV	1	Grade 1 (Mild)
AESEV	2	Grade 2 (Moderate)
AESEV	3	Grade 3 (Severe)
AESEV	4	Grade 4 (Potentially life-threatening)
AESEV	5	Grade 5 (Death)
BSSPEC	1	Plasma for archive
BSSPEC	2	Blood for PK
BSSPEC	3	CVF for PK
BSSPEC	4	CVF for PD
BSSPEC	5	CVF for microflora
BSSPEC	6	Rectal fluid for PK
BSSPEC	7	Rectal fluid for PD
BSSPEC	8	Rectal fluid for microbiome
BSSPEC	9	Rectal enema prior to biopsy collection
BSSPEC	10	Rectal tissue for PK
BSSPEC	11	Rectal tissue for PD
BSSPEC	12	Rectal tissue for biomarkers
BSSTORE	1	Stored
BSSTORE	2	Not stored
CMDOSFRQ	PRN	PRN
CMDOSFRQ	QD	QD
CMDOSFRQ	BID	BID
CMDOSFRQ	TID	TID
CMDOSFRQ	QID	QID
CMDOSFRQ	QM	QM
CMDOSFRQ	QH	QH
CMDOSFRQ	ONCE	ONCE
CMDOSFRQ	OTHER	Other
CMDOSU	g	Grams
CMDOSU	ug	Microgarms
CMDOSU	mg	Milligrams
CMDOSU	ml	Milliliters
CMDOSU	CAPSULE	Capsules
CMDOSU	gtt	Drops
CMDOSU	PUFF	Puffs
CMDOSU	SACHET	Sachets
CMDOSU	SUPPOSITORY	Suppository
CMDOSU	TABLET	Tablets
CMDOSU	UNIT	Units
CMDOSU	UNKNOWN	Unknown
CMDOSU	OTHER	Other
CMROUTE	IHL	Inhalation
CMROUTE	IM	Intramuscular
CMROUTE	IV	Intravenious
CMROUTE	OTHER	Other
CMROUTE	PO	Oral
CMROUTE	REC	Rectal
CMROUTE	SC	Subcutaneous
CMROUTE	TOP	Topical
CMROUTE	VAG	Vaginal
DSTERM	1	Scheduled exit visit/end of study
DSTERM	2	Death
DSTERM	3	Participant refused further participation
DSTERM	4	Participant is unwilling or unable to comply with required study procedures
DSTERM	5	Lost to follow-up
DSTERM	6	Investigator decision
DSTERM	7	Participant refused further study product use
DSTERM	8	Unable to contact participant
DSTERM	9	HIV infection
DSTERM	10	Early study closure
DSTERM	11	Protocol deviation
DSTERM	12	Adverse event
DSTERM	13	Preenancy
DSTERM	14	Withdrawal of consent by participant (remove for HVTN)
DSTERM	15	Study terminated by sponsor
DSTERM	16	One or more reactive HIV test results or acute HIV infection suspected
DSTERM	17	Participant unable to adhere to visit schedule (HVTN)
DSTERM	18	Participant relocated, no follow-up planned (HVTN)
DSTERM	19	Reactogenicity symptoms (HVTN)
DSTERM	99	Other, specify
DSTRTTERM	1	Scheduled study product use period completed
DSTRTTERM	2	Death
DSTRTTERM	3	Participant refused further participation
DSTRTTERM	4	Participant is unwilling or unable to comply with required study procedures
DSTRTTERM	5	Lost to follow-up (remove for HVTN)
DSTRTTERM	6	Investigator decision
DSTRTTERM	7	Participant refused further study product use
DSTRTTERM	8	Unable to contact participant
DSTRTTERM	9	HIV infection
DSTRTTERM	10	Early study closure
DSTRTTERM	11	Protocol deviation
DSTRTTERM	12	Adverse event
DSTRTTERM	13	Pregnancy
DSTRTTERM	14	Withdrawal of consent by participant (remove for HVTN)
DSTRTTERM	15	Study terminated by sponsor
DSTRTTERM	16	One or more reactive HIV test results or acute HIV infection suspected
DSTRTTERM	17	Participant unable to adhere to visit schedule (HVTN)
DSTRTTERM	18	Participant relocated, no follow-up planned (HVTN)
DSTRTTERM	19	Reactogenicity symptoms (HVTN)
DSTRTTERM	99	Other, specify
DVDECOD	1	Inappropriate enrollment
DVDECOD	2	Failure to follow randomization or blinding procedures
DVDECOD	3	Study product management deviation
DVDECOD	4	Study product dispensing error
DVDECOD	5	Study product use/non-use deviation
DVDECOD	6	Study product sharing
DVDECOD	7	Study product not returned
DVDECOD	8	Conduct of non-protocol procedure
DVDECOD	9	Improper AE/EAE
DVDECOD	10	Unreported AE
DVDECOD	11	Unreported EAE
DVDECOD	12	Breach of confidentiality
DVDECOD	13	Physical assessment deviation
DVDECOD	14	Lab assessment deviation
DVDECOD	15	Mishandled lab specimen
DVDECOD	16	Staff performing duties that they are not qualified to perform
DVDECOD	17	Questionnaire administration deviation
DVDECOD	18	Counseling deviation
DVDECOD	19	Use of non-IRB/EC-approved materials
DVDECOD	20	Use of excluded concomitant medications, devices, or non-study products
DVDECOD	21	Informed consent process deviation
DVDECOD	22	Visit completed outside of window
DVDECOD	99	Other
ETHNIC	1	Hispanic or Latino
ETHNIC	2	Not Hispanic or Latino
FAGESAGETYP	1	Ballard
FAGESAGETYP	2	Dubowitz
FAGESAGETYP	3	Other
GTLTEQ	1	>
GTLTEQ	2	<
GTLTEQ	3	=
HIV12AB	1	HIV-1 indeterminate
HIV12AB	2	HIV-2 indeterminate
HIV12AB	3	HIV-1 positive
HIV12AB	4	HIV-2 positive
HIV12AB	5	HIV-2 positive with HIV-2 crossreactivity
HIV12AB	6	HIV positive undifferentiated (untypeable)
HIVRNAPCR	Depends on the PCR Kit	20
HIVRNAPCR	Depends on the PCR Kit	40
IESTATUS	1	Elieible and enrolled
IESTATUS	2	Elgible/Not enrolled
IESTATUS	3	Ineligible
IESTATUS	4	Incomplete Screening
LBSEV	1	Grade 1 (Mild)
LBSEV	2	Grade 2 (Moderate)
LBSEV	3	Grade 3 (Severe)
LBSEV	4	Grade 4 (Potentially life-threatening)
LBSEV	95	Not aradable
MBFNLHIV	1	HIV uninfected
MBFNLHIV	2	HIV infected
MBFNLHIV	3	Pending
MBREFID	1	Abbott M2000
MBREFID	2	Roche TaqMan
MBREFID	3	Gene Xpert
MHSEV	1	Grade 1 (Mild)
MHSEV	2	Grade 2 (Moderate)
MHSEV	3	Grade 3 (Severe)
MHSEV	4	Grade 4 (Potentially life-threatening)
NABND	1	Not Done
NABND	2	Normal
NABND	3	Abnormal
PECECTO	1	0%
PECECTO	2	1-25%

PECECTO	3	26-50%
PECECTO	4	51-75%
PECECTO	5	76-100%
PECECTO	6	Not done
PERES	1	Not done
PERES	2	Abnormal findings
PERES	3	No abnormal findings
PEVGABDX	1	Slight
PEVGABDX	2	Moderate
PEVGABDX	3	Pooling
POCABIND	1	Yes
POCABIND	2	No
POCABIND	3	Not assessed
POCABIND	4	Unknown
POMETHOD	1	C-section
POMETHOD	2	Standard vaginal
POMETHOD	3	Operative vaginal
POMETHOD	4	Vaginal
POOUTCOME	1	Full term live birth (>=37 weeks)
POOUTCOME	2	Premature live birth (<37 weeks)
POOUTCOME	3	Stillbirth/intrauterine fetal demise (>=20 weeks)
POOUTCOME	4	Spontaneous abortion (<20 weeks)
POOUTCOME	5	Ectopic pregnancy
POOUTCOME	6	Therapeutic/elective abortion
POOUTCOME	7	Other
POPLACE	1	Home
POPLACE	2	Hospital
POPLACE	3	Clinic
POPLACE	4	Unknown
POPLACE	5	Other
POS/NEG	1	Positive
POS/NEG	2	Negative
POSEX	M	Male
POSEX	F	Female
RPEDLVR	1	Last menstrual period
RPEDLVR	2	Initial ultrasound <20 weeks
RPEDLVR	3	Initial ultrasound >=20 weeks
RPEDLVR	4	Physical examination
RPEDLVR	5	Conception date by assisted reproduction
RPEDLVR	6	Other
SCSEXORIEN	1	Heterosexual
SCSEXORIEN	2	Homosexual
SCSEXORIEN	3	Bisexual
SCSEXORIEN	4	Asexual
SCSEXORIEN	5	Additional category, specify
SCSEXORIEN	6	Not sure
SCSEXORIEN	7	Prefer not to answer
SEX	M	Male
SEX	F	Female
VISIT	1	Screening
VISIT	2	Enrollment
VISIT	3	Visit 3
VISIT	4	Visit 4
VISIT	5	Visit 5
VISIT	6	Visit 6
VISIT	7	Visit 7
VISIT	8	Visit 8
VISIT	9	Visit 9
VISIT	10	Visit 10
VISIT	11	Visit 11/Final Contact
VISIT	12	Interim Visit
Yes/No	Y	Yes
Yes/No	N	No
Yes/No/NS/UNK	Y	Yes
Yes/No/NS/UNK	N	No
Yes/No/NS/UNK	NS	Not assessed
Yes/No/NS/UNK	UNK	Unknown
PODELIVTYP	1	C-section
PODELIVTYP	2	Standard vaginal
PODELIVTYP	3	Operative vaginal
PODELIVTYP	4	Vaginal
IETEST	1	I1. Individuals who are 18 years of age or older at Screening
IETEST	2	I2. Able and willing to provide written informed consent to be screened for and enrolled in MTN-039
IETEST	3	I3. HIV-1/2 uninfected at Screening and Enrollment and willing to receive HIV test results
IETEST	4	I4. Able and willing to provide adequate locator information
IETEST	5	I5. Able to communicate in spoken and written English
IETEST	6	I6. Available for all visits and able and willing to comply with all study procedural requirements
IETEST	7	I7. In general good health at Screening and Enrollment, as determined by the site IoR or designee
IETEST	8	I8. At Screening, history of consensual RAI at least once in lifetime per participant report
IETEST	9	I9. Willing not to take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation (including the time between Screening and Enrollment)
IETEST	10	I10. Willing to comply with abstinence and other protocol requirements
IETEST	11	I11. For participants of childbearing potential: a negative pregnancy test at Screening and Enrollment
IETEST	12	I12. For participants of childbearing potential: Per participant report at Enrollment, using an effective method of contraception for at least 30 days (inclusive) prior to Enrollment and intending to use an effective method for the duration of study participation
IETEST	13	E1a. Hemoglobin Grade 1 or higher
IETEST	14	E1b. Platelet count Grade 1 or higher
IETEST	15	E1c. Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher
IETEST	16	E1d. Serum creatinine >1.3× the site laboratory upper limit of normal (ULN)
IETEST	17	E1e. International normalized ratio (INR) >1.5× the site laboratory ULN
IETEST	18	E1f. History of inflammatory bowel disease by participant report
IETEST	19	E2a. Anticipated use of and/or unwillingness to abstain from anticoagulant medications during study participation
IETEST	20	E2b. Anticipated use of and/or unwillingness to abstain from non-study rectally-administered medications and any products containing N-9 during study participation
IETEST	21	E3. Known adverse reaction to any of the components of the study product
IETEST	22	E4. Use of pre-exposure prophylaxis (PrEP) for HIV prevention within 3 months prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from PrEP during trial participation
IETEST	23	E5. Use of post-exposure prophylaxis (PEP) for potential HIV exposure within 6 months prior to Enrollment
IETEST	24	E6. Condomless RAI and/or penile-vaginal intercourse with a partner who is known to be HIV-positive or whose status is unknown in the 6 months prior to Enrollment
IETEST	25	E7. History of transactional sex in the 12 months prior to Enrollment
IETEST	26	E8. Non-therapeutic injection drug use or use of non-therapeutic, non-injection stimulant drugs in the 12 months prior to Enrollment
IETEST	27	E9. Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines within 30 days of the Enrollment Visit
IETEST	28	E10a. Diagnosis or treatment of an anogenital STI in the 3 months prior to enrollment (including window between Screening and Enrollment).
IETEST	29	E10b. Symptoms, clinical or laboratory diagnosis of active pharyngeal, anorectal, or reproductive tract infection (RTI) requiring treatment per current CDC guidelines
IETEST	30	E10c. Current symptomatic urinary tract infection (UTI).
IETEST	31	E11. For participants of childbearing potential: Pregnant or breastfeeding at either Screening or Enrollment or planning to become pregnant during study participation
IETEST	32	E12. For participants of childbearing potential: Last pregnancy outcome 90 days or less prior to Screening
IETEST	33	E13. Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate the interpretation of study outcome data, or otherwise interfere with achieving the study objectives including any significant uncontrolled active or chronic medical condition.
SVRSNMSD	1	Unable to contact participant
SVRSNMSD	2	Participant unable to schedule visit within window
SVRSNMSD	3	Participant refused visit
SVRSNMSD	4	Participant incarcerated
SVRSNMSD	5	Participant admitted to healthcare facility
SVRSNMSD	6	Participant withdrew from study
SVRSNMSD	7	Participant deceased
SVRSNMSD	99	Other
ECREASOC	1	Reactive rapid HIV test
ECREASOC	2	Adverse Event
ECREASOC	3	Reported use of PEP or PrEP
ECREASOC	4	Pregnancy
ECREASOC	5	Breastfeeding
ECREASOC	6	Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee
ECREASOC	99	Other
ECCONTYN	1	Yes
ECCONTYN	2	No - Hold continuing for another reason
ECCONTYN	3	No - Early termination
ECCONTYN	4	No - Hold continuing at scheduled PUEV
ECCONTYN	5	No - Permanently discontinued
LBTEST1	1	Non-reactive
LBTEST1	2	Reactive
LBTEST1	3	Not reported
LBTEST2	1	Positive
LBTEST2	2	Negative
LBTEST2	3	Indeterminate
LBTEST2	4	Not done
LBMETHOD	1	Alere/TM HIV Combo
LBMETHOD	2	Oraquick ADVANCE HIV-1/2
LBMETHOD	3	Uni-Gold Recombigen HIV-1/2
LBMETHOD	4	Alere Determine
LBMETHOD	5	Other
LBTEST3	1	Antibody positive
LBTEST3	2	Antigen postive
LBTEST3	3	Antibody and antigen positive
LBTEST3	4	Negative
ENTPT	1	Group 1
ENTPT	2	Group 2
MVINTVISIT	1	Visit 2
MVINTVISIT	2	Visit 4
MVINTVISIT	3	Visit 5
MVINTVISIT	4	Visit 6
MVINTVISIT	5	Visit 7
MVINTVISIT	6	Visit 8
MVINTVISIT	7	Visit 9
MVINTVISIT	8	Visit 10
MVINTVISIT	9	Visit 11/Final Contact
QSVER	1	Visit 2 Baseline CASI
QSVER	2	Visit 4 Follow-Up CASI
QSVER	3	Visit 8 Follow-Up CASI
QSVER	4	Visit 10 IDI
VISIT1	1	Visit 3
VISIT1	2	Visit 7
ECDOSE	1	1 TAF/EVG insert
ECDOSE	2	2 TAF/EVG inserts